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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,528	03/17/2004	Lajos Hegedus	01662/53303	3513

26646 7590 01/09/2007

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,528	HEGEDUS ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 42-60, drawn to a pharmaceutical composition comprising a therapeutically active compound binding to plasma protein, classification unknown.

II. Claims 61 and 63, drawn to a method of treating cancer comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount of paclitaxel or camptothecin, classified in at least class 514, subclass 449.

III. Claim 62, drawn to a method of treating fungal infection comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount of amphotericin B, classified in at least class 514, subclass 28.

IV. Claim 64, drawn to a method of treating hypercholesterolemia or hyperlipidemia comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount of gemfibrozil, classified in at least class 514, subclass 49.

V. Claim 65, drawn to a method of treating immunosuppression comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount of cyclosporine A, classified in at least class 514, subclass 11.

VI. Claim 66, drawn to a method of treating anxiety or pain comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount of propofol, classified in at least class 514, subclass 731

The inventions are distinct, each from the other because of the following reasons:

a. Inventions I and (II-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of invention I can be used in assays for the identification of agonist and antagonist of the polypeptide.

Additionally, searching the inventions of Groups I and (II-VI) together would impose serious search burden. The inventions of I and (II- VI) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the various compounds which bind the plasma protein and method of use are not coextensive.

b. Inventions II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions II-VI are different methods requiring different methods steps, wherein each is not required, one for another. For example, Invention II requires search and consideration of a method of treating cancer comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount paclitaxel or camptothecin, which is not required by the other invention. Invention III requires search and consideration of a method of treating fungal infection comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount amphotericin B, which is not required by the other invention. Invention IV requires search and consideration of a method of treating hypercholesterolemia or hyperlipidemia comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount gemfibrozil, which is not required by the other invention. Invention V requires search and consideration of a method of treating immunosuppression comprising administering to a patient in need thereof

a pharmaceutical composition comprising a therapeutically effective amount cyclosporine A, which is not required by the other invention. Invention VI requires search and consideration of method of treating anxiety or pain comprising administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount propofol, which is not required by the other invention. Furthermore, the distinct methods require separate, distinct, and non-overlapping coextensive searches. As such, it would be burdensome to search the inventions of Groups II-VI together.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different classification and different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. This application contains claims directed to the following patentably distinct species:

A. The pharmaceutical compositions comprising a therapeutically active compound listed below have different modes of action and treat different diseases (different pathologies and different mechanisms). The pharmaceutical composition comprises:

A-a. amphotericin B;

A-b. an adriamicine analogue;

A-c. apazone;

A-d. azathioprin;

A-e. bromazepam;

A-f. camptothecin;

A-g. carbamazepin;

A-h. clonazepam;

A-i. cyclosporine A;

A-j. diazepam;

A-k.dicumarol;

A-l. digitoxin;

A-m. dipyridamole;

A-n. disopyramide;

A-o. flunitrazepam;

A-p. gemfibrozil;

A-q. ketochlorin;

A-r. ketoconazole;

A-s. miconazole;

A-t. niflumic acid;

A-u. oxazepam;

A-v. paclitaxel;

A-w. phenobarbital;

A-x. phenytoin;

A-y. progesterone;

A-z. propofol;

A-aa. ritonavir;

A-ab. sulfinpyrazone;

A-ac. suprofene;

A-ad. tacrolimus;

A-ae. tamoxifen;

A-af. taxonoid;

A-ag. testosterone;

A-ah. tirilazad;

A-ai. trioxsalen;

A-aj. valproic acid;

A-ak. warfarin

The species are independent or distinct because each of the of the compounds (A-a)-(A-ak) have different mechanisms of action and have different structures. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for a pharmaceutical composition comprising warfarin, may not result in relevant art with respect to composition comprising cyclosporine A.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42-52 and 54-60 are generic. Applicant is also required to disclose a single molecular embodiment from claims 46 and 58, wherein Applicant identifies a single species from the listed subgenuses of the claims. For example, warfarin (species) is an anticoagulant (subgenus).

B. The pharmaceutical compositions comprising the following plasma proteins listed below have different structures and are involved different diseases (different pathologies and different mechanisms). The plasma protein comprises:

B-a. serum albumin;

B-b. an immunoglobin;

B-c. a glycoprotein;

B-d. an interferon;

B-e. an interleukin

The species are independent or distinct because each of the of the plasma proteins (B-a)-(B-e) have different mechanisms of action and have different structures. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for a pharmaceutical composition comprising an interferon, may not result in relevant art with respect to composition comprising an immunoglobulin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42-48, 50-54, and 56-66 and are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

4. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant in addition to electing from Inventions I-VI, one species from therapeutically active compound group (A) and plasma protein group (B) must also be chosen to be considered fully responsive.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647,
September 19, 2006

Jegatheesan Seharaseyon
Patent Examiner